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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/848,777	AUDEH ET AL.
Examiner	Art Unit	
Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 October 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 and 30-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-21 and 30-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, applicant's amendment has incorporated claims 1-15 into Group II, so claims 1-21 and 30-32 are examined herein.

Claim Objections

2. Claims 1-15 are objected to because of the following informalities: they are improperly dependent because they depend, either directly or indirectly from a higher numbered claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 14-15, 18-21, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 9 recites the limitation "said more than one species". There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should depend from claim 7 or 8, rather than claim 1.

6. Claim 14 recites the limitation "the concentration" in lines 3 and 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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7. Claim 15 recites the limitation "the concentration" in 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 18 recites the limitation "the concentration" in lines 3 and 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 19-21 are rejected as vague and indefinite for the recitation of a diameter less than a certain length. The ranges recited in the claims include zero, but a diameter of 0 means that there is no matrix present.

10. Claim 31 is rejected as vague and indefinite for the recitation of a diameter less than 10 uM because this range includes zero, but a diameter of 0 means that there is no particle present.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

12. Claims 1-6, 10, 14, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Ness et al. (US Pat. 5,667,976). The reference discloses solid supports for nucleic hybridization assays, wherein nylon coated magnetic beads may be used (abstract and Col. 14). Oligonucleotides are immobilized via covalent attachment onto the beads and serve as probes (abstract and claim 1). The beads may be employed free in solution (abstract). The reference

also discloses that the oligonucleotides immobilized on the beads can serve as electrophiles for the covalent attachment of proteins and antibodies. In addition, labels, such as colored labels (dyes), may be used in the hybridization assays.

13. Claims 1, 3-4, 6-9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al. (US Pat. 5,194,372). The reference discloses methods for detecting disorders, wherein fine particles in solution have at least two types of nucleic acid singles stranded probes immobilized thereon. The probes are complementary to first and second regions, respectively, and are exclusive of each other (see claim 1).

14. Claims 1, 3-4, 6-10, 13-16, 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Delair et al. (US Pat. 6,033,853). The reference discloses a kit for detecting a nucleic acid sequence comprising a labeled nucleotide probe and a reagent consisting essentially of a suspension of insoluble particles on which at least one series of oligonucleotides are immobilized. The kit may be used in hybridization assays (abstract). The size of the particle may range from 50 nm to 5um (claim 7). The oligonucleotide probes may be immobilized on the particle via covalent binding or adsorption, and the label may be any known in the art, such as colored labels.

15. Claims 1, 3-6, 10, 13, 16, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawaguchi et al. (US Pat. 5,122,600). The reference discloses DNA immobilized microspheres, wherein the particle has a diameter of 0.1-50 uM. Protein may be adsorbed to the DNA immobilized particles for protein purification. DNA may be attached to the particles via adsorption or covalent attachment.

16. Claims 1, 3, 10, 12, 16, and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (WO 00/00808). The reference discloses colloidal particles used in

sensing arrays, wherein the conductive portion may comprise nanoparticles that are optionally stabilized with organic ligands. The particle size can be manipulated and controlled (page 9). The ligands may be attached by various methods, including covalent and electrostatic attachment (page 10). The nanoparticles range in size from 1 nm to about 50 nm (page 10). The nanoparticles are dispersible in a wide variety of organic solvents (page 12).

17. Claims 1, 3-9, 14-16, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Seul (WO 97/40385). The reference discloses the manipulation of colloidal particles, wherein the particles may be 1 or 10 microns in diameter (page 55). A plurality of types of molecules may be attached to the surfaces of the particles, wherein each particle has a plurality of particles of one type (page 58). The molecules may be oligonucleotides or protein. The particle or beads may also be labeled by any known conventional label, including colored labels.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seul (WO 97/40385), Lewis et al. (WO 00/00808), Kawaguchi et al., or Delair et al. (US Pat. 6,033,853).

The references teach colloidal particles, as discussed above under 35 USC 102.

However, the references do not teach the colloids in powder form.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove the liquid in the colloidal suspensions of Seul, Lewis et al., Kawaguchi et al., or Delair et al. and arrive at a powdered form because powder is well known in the art to have greater stability and shelf life in comparison to a liquid form. In addition, such a form is easier to package in a kit, which provides increased convenience and economy. Also, a powder form may be easily reconstituted, as necessary, prior to use.

22. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al. (US Pat. 5,194,372) or Van Ness et al. (US Pat. 5,667,976).

The references teach colloidal particles, as discussed above under 35 USC 102.

However, the references do not teach the colloids in powder form.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove the liquid in the colloidal suspensions of Nagai et al. or Van Ness et al.

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and arrive at a powdered form because powder is well known in the art to have greater stability and shelf life in comparison to a liquid form. In addition, such a form is easier to package in a kit, which provides increased convenience and economy. Also, a powder form may be easily reconstituted, as necessary, prior to use.

23. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seul (WO 97/40385) or Nagai et al. (US Pat. 5,194,372). The references teach colloidal particles, as previously discussed. However, the references do not teach the way in which molecules are attached to the particles.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize molecules to the particles of Seul or Nagai et al. via covalent, non-covalent, electrostatic, or adsorptive techniques because all are well known immobilization methods in the art, and one of skill would have had a reasonable expectation of success in using any of these methods to immobilize the molecules onto particles.

24. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (WO 00/00808). The reference teaches colloidal particles, as previously discussed. However, the reference does not teach non-covalent binding or adsorption to attach ligands.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize molecules to the particles of Lewis et al. via non-covalent or adsorptive techniques because all are well known immobilization methods in the art, and one of skill would have had a reasonable expectation of success in using any of these methods to immobilize the molecules onto particles. Further, Lewis et al. state that covalent and electrostatic attachment are only representative techniques and are non-limiting.

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25. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi et al. (US Pat. 5,122,600). The reference teaches colloidal particles, as previously discussed. However, the reference does not teach non-covalent or electrostatic binding to attach molecules.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize molecules to the particles of Kawaguchi et al. via non-covalent or electrostatic binding because all are well-known immobilization methods in the art, and one of skill would have had a reasonable expectation of success in using any of these methods to immobilize the molecules onto particles. Further, Kawaguchi et al. state that the immobilization technique is not critical.

26. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delair et al. (US Pat. 6,033,853). The reference teaches colloidal particles, as previously discussed. However, the reference does not teach non-covalent or electrostatic binding to attach molecules.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize molecules to the particles Delair et al. via non-covalent or electrostatic binding because all are well-known immobilization methods in the art, and one of skill would have had a reasonable expectation of success in using any of these methods to immobilize the molecules onto particles.

27. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness et al. (US Pat. 5,557,976). The reference teaches colloidal particles, as previously discussed. However, the reference does not teach non-covalent or electrostatic binding, or adsorption to attach molecules.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of

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the invention to immobilize molecules to the particles Van Ness et al. via non-covalent or electrostatic binding, as well as adsorption because all are well-known immobilization methods in the art, and one of skill would have had a reasonable expectation of success in using any of these methods to immobilize the molecules onto particles.

Conclusion

Claims 1-21 and 30-32 are rejected.

Reference: Dale et al. is cited as art of interest for teaching particles with attached biomolecules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

*** *KP*
December 30, 2002

Long Le
LONG V. LE
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12/30/02